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PUBLIC HEARING COMMENTS BEFORE THE
FDA ADVISORY COMMITTEE FOR REPRODUCTIVE HEALTH DRUGS:
New Drug Application (NDA) 22-474,
Ulipristal Acetate Tablets (30 mgs) - "Ella"
Emergency Contraceptive

Presented by:
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June 17, 2010

For over 30 years, NHeLP, a national public interest law firm, has sought to improve health care and protect the right to health for America's low-income populations, communities of color, women, and other uninsured or under-insured communities, with our primary emphasis on working to support the Medicaid program and other safety-net programs through legislative and policy advocacy, technical support, and class action litigation.

On behalf of NHeLP, thank you for the opportunity to present comments regarding the accessibility of FDA-approved contraceptives for low-income populations. I request that my written comments and supporting materials be submitted as part of today's public hearing record.

I. Background Information and Issue:

- Family planning is essential to maintaining women's health (particularly the health of women with low-incomes and health disparities), which is negatively impacted by untimely access to family planning information and supplies. This impact is felt by the 17.4 million low-income women who were considered to be in need of publicly funded contraceptive services and supplies (e.g., covered through Medicaid or provided in Title X family planning clinics), [according to the Guttmacher Institute, 2008].[i] Family planning is also featured as a focus area of the *Healthy People 2010* health promotion objectives, established by the U.S. Department of Health and Human Services (HHS).[ii]
- The outcome of untimely access to contraceptives and family planning information is reflected in significant and troubling rates of sexually transmitted diseases, unintended

pregnancies, and poor health and birth outcomes for women with chronic diseases and health disparities.[iii] For example:

- For women with chronic health conditions, such as diabetes, cardiovascular disease, epilepsy, and lupus, it is particularly important for them to use effective contraceptive methods to prevent pregnancy until their chronic condition can be controlled [Centers for Disease Control and Prevention, *Recommendations to Improve Preconception Health and Health Care*, 2005].[iv]

- The scope of health disparities is further demonstrated by examining prevalence rates of type 2 diabetes. All minorities (except Alaskan Natives) have a two to six times greater prevalence rate than that of the white population for this disease. [HHS, Agency for Healthcare Research and Quality].[v]

- The primary issue of concern is the following current requirement: For states to obtain federal reimbursement, the Medicaid program requires a prescription for family planning drugs and supplies that are typically sold over-the-counter (OTC), including condoms, spermicides, and other OTC products. *If the FDA approves the current new drug application (Ella) as an emergency contraceptive (EC), and eventually for OTC use – like its predecessor Plan B® (levonorgestrel) – millions of women would have increased access to an additional important contraceptive, <u>except for low-income women</u>. Specifically, Medicaid beneficiaries are currently subject to the prescription requirement in order to get OTC products, which would effectively delay and often block OTC access to Ella and other contraceptives.*[vi]

- The prescription requirement adds costly and unnecessary provider visits, and creates barriers to OTC family planning drugs and supplies for Medicaid beneficiaries (who cannot afford to pay out-of-pocket costs for contraception), which results in unequal access to contraception and other prevention efforts for low-income communities.

II. <u>Background on Medicaid Coverage of Outpatient and OTC Drugs:</u>

Medicaid is a federal health entitlement program primarily for low-income populations that is administered by the states on a voluntary basis. Currently, federal Medicaid coverage of prescription drugs is an optional (not a required or mandatory) service.

- States are free to exclude or restrict coverage of outpatient drugs,[vii] which are drugs and supplies normally obtained at a pharmacy, not on an in-patient hospital basis.
- However, all states participate in the Medicaid prescription drug program,[viii] and all states cover outpatient drugs.[ix]

States also have the option of covering OTC drugs as outpatient drugs if a physician or other authorized prescriber orders (prescribes) the drugs and supplies.[x] Many state Medicaid programs cover some OTC drugs, but in most cases with limited coverage or coverage with restrictions.[xi]

Medicaid coverage of OTC contraceptive drugs and supplies without a prescription will reduce unintended pregnancies and sexually transmitted diseases and infections. Implementing true OTC access to male and female condoms and other contraceptive drugs and supplies, will reduce health care costs and promote health and well-being, and healthier pregnancies when women decide to become parents.[xii]

III. Proposed Solution: Expand Access to OTC Drugs and Supplies for Low-Income Individuals on Medicaid by Amending the Social Security Act (§ 1927(k))

Although amending the Medicaid Act is not within the FDA's jurisdiction, NHeLP would encourage the FDA to inform other divisions in the Department of Health and Human Services (e.g., the Centers for Medicare & Medicaid Services) that have this authority, and support corresponding efforts to correct this inequity.

Specifically, NHeLP supports changing the Medicaid law in order to equalize and increase access to a wider variety of FDA-approved OTC contraceptives for low-income communities. An example of a proposed change to the Medicaid law is included below:

> Soc. Sec. Act § 1927(k) definitions:
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> (2) Covered outpatient drug. – Subject to the exceptions in paragraph (3) and (4), the term "covered outpatient drug" means –
>
> (4) Non prescription drugs. – If a State plan for medical assistance under this title includes coverage of prescribed drugs as described in section 1905(a)(12) and permits coverage of drugs which may be sold without a prescription (commonly referred to as "over-the-counter" drugs), if

they are prescribed by a physician (or other person authorized to prescribe under State law), such as drug shall be regarded as a covered outpatient drug, except that, family planning drugs and supplies as provided in section 1905(a)(4)(C) which are FDA-approved for over-the-counter sale shall be considered covered outpatient drugs without the requirement of a prescription.

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[i] Guttmacher Institute, Contraceptive Needs and Services: National and State Data, 2008 Update, http://www.guttmacher.org/pubs/win/contraceptive-needs-2008.pdf.

[ii] U.S. Department of Health and Human Services, HEALTHY PEOPLE 2010: UNDERSTANDING AND IMPROVING HEALTH (2000). Goal 9 of Healthy People 2010 is, "Improve pregnancy planning and spacing and prevent unintended pregnancy." Specific indicators include increasing the proportion of women at risk for unintended pregnancy who use contraceptives to 100 percent, and increasing the proportion of teens who use contraceptive methods that both prevent pregnancy and sexually transmitted diseases.

[iii] *See generally* Centers for Disease Control and Prevention, *Sexually Transmitted Diseases, STDs and Pregnancy: CDC Fact Sheet*, accessed at http://www.cdc.gov/std/STDFact-STDs&Pregnancy.htm; Guttmacher Institute, *Facts on Publicly Funded Contraceptive Services in the United States*, February 2009, accessed at http://www.guttmacher.org/pubs/fb_contraceptive_serv.html; K. Johnson, S.F. Posner, J. Biermann *et al, Recommendations to Improve Preconception Health and Health Care – United States, A Report of the CDC/ATSDR Preconception Care Work Group and the Select Panel on Preconception Care*, MMWR MORBIDITY AND MORTALITY WKLY. REP. RECOMMENDATIONS AND REP. (2006); L.B. Finer and S.K. Henshaw, *Disparities in Rates of Unintended Pregnancies in the United States, 1994 and 2001*, 38 PERSP. ON SEXUAL AND REPRO. HEALTH, 90-6 (2006).

[iv] National Health Law Program, *Health Care Refusals: Undermining Quality Care for Women*, 2010.

[v] U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, "Diabetes Disparities Among Racial and Ethnic Minorities," *Fact Sheet*, http://www.ahrq.gov/research/diabdisp.htm.

- Different studies found that African Americans are from 1.4 to 2.2 times more likely to have diabetes than white persons.
- Hispanic Americans have a higher prevalence of diabetes than non-Hispanic people, with the highest rates for type 2 diabetes among Puerto Ricans and Hispanic people living in the Southwest and the lowest rate among Cubans.
- The prevalence of diabetes among American Indians is 2.8 times the overall rate.
- Major groups within the Asian and Pacific Islander communities (Japanese Americans, Chinese Americans, Filipino Americans, and Korean Americans) all had higher prevalences than those of whites.

Ibid.

[vi] *See also* Pharmacy Access Partnership, *Birth Control Within Reach: A National Survey of Women's Attitudes and Interests in Pharmacy Access to Hormonal Contraception* (2005); http://www.pharmacyaccess.org/pdfs/ExecutiveSummary.pdf. A Pharmacy Access Partnership survey determined that about half of low-income women (40 percent) not using the pill, patch or ring indicated that they would start using those methods, *if* they were available without a prescription.

[vii] 42 U.S.C. § 1396r-8(d)(l)(B)(i); *id.* § 1396r-8(d)(4)(c).

[viii] 42 U.S.C. § 1396a(a)(10), 1396d(a)(2006). *See generally* National Health Law Program, *Q & A: Medicaid Coverage of Outpatient Prescription Drugs*, Feb. 26, 2007, accessed at http://www.healthlaw.org/library/item.134440.

[ix] 42 U.S.C. § 1396d(a)(12).

[x] 42 U.S.C. § 1396r-8(k)(4).

[xi] Congressional Research Service, *Prescription Drug Coverage Under Medicaid*, Updated Feb. 6, 2008, citing *Pharmaceutical Benefits Under State Medical Assistance Programs* 2005/2006, National Pharmaceutical Council at http://www.npcnow.org/resources/PDFs/medicaid2005/05-06Section4.pdf.

[xii] New York State determined that eliminating the federal requirement for a prescription order prior to dispensing over-the-counter emergency contraception (and using state funds to pay for these drugs) would yield a conservative gross annual cost savings of $3.2 million (with an estimated $1.5 million in savings each for the state and federal governments). The methodology was based on avoiding the cost of prenatal care, delivery, and associated delivery costs in New York State, by providing emergency contraception OTC instead. N.Y. Reg., Jan. 23, 2008, at 8.